

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOPURE CORPORATION)
SECURITIES LITIGATION)
_____)

Master Docket No. 1:03-CV-12628 (NG)

Assigned to Judge Nancy Gertner

**2-PAGE SUR-REPLY IN OPPOSITION
TO PLAINTIFFS' MOTION TO AMEND**

1. Defendants have cited FDA Guidances and case law dictating that FDA “concerns” (not conclusions) about “safety” (an FDA term of art concerning risk/benefit analysis *within a proposed indication*) are a part of routine scientific dialogue that should not be disclosed. In response, Plaintiffs ask the Court to assume (without support) that the FDA’s clinical hold in a *trauma* study was material to Biopure’s *orthopedic surgery* BLA.

The length of the complaint and hyperbole in Plaintiffs’ brief should not obscure a simple fact. *Nowhere* do Plaintiffs plead *any* FDA communication stating that safety concerns in trauma meant safety concerns (let alone conclusions) in orthopedic surgery. In fact, the FDA’s BLA letter of July 30, 2003, attached to the complaint, and which Plaintiffs contend was a “complete response” to the BLA, negates any such inference. In thirty four pages, the FDA did not once state a conclusion that Hemopure was unsafe.

2. In response to case law dictating that SEC-copied allegations pled on information and belief cannot be considered by this Court and they fail to satisfy the PSLRA, Plaintiffs cite a single case, *De La Fuente v. DCI telecom., Inc.*, 259 F. Supp. 2d 250 (S.D.N.Y. 2003). Plaintiffs fail to point out that *De La Fuente* said only, in dicta, that a securities’ plaintiff’s copying of SEC allegations *would not result in Rule 11 sanctions*. The decision did not even involve a Rule 12(b)(6) motion under the PSLRA, and has no applicability here. The Court did *not* hold or even say that such allegations can be pleaded to support a motion to amend or defeat a motion to

dismiss. The motion to amend should be denied and the SEC-copied allegations should be ignored.

3. It should be noted that the Plaintiffs in their opposition do not defend their theory that Defendants committed fraud by not disclosing that the FDA's July 30, 2003 BLA letter -- which nowhere uses the phrase "complete response letter" -- was a complete response letter.

4. It should also be noted that the Plaintiffs have no explanation for why the complaint pleads nothing to support any inference of *scienter* for Defendants Sanders, Crout, Rausch and Richards. The Plaintiffs are similarly silent on identifying a single allegation that could show any intent to deceive (as opposed to merely challenging a judgment call) for Defendants Moore and Richman. The Plaintiffs' mere assumptions cannot substitute for facts giving rise to a strong inference of *scienter*.

5. Incidentally, the SEC's complaint against individuals Moore and Richman contains non-*scienter* claims. These claims are not subject to the "same pleading standard" as is this complaint, as Plaintiffs erroneously assert. Rather, they are subject to Rule 8.

January 31, 2006

Respectfully submitted,

**BIOPURE CORPORATION, THOMAS A.
MOORE, HOWARD P. RICHMAN, RONALD
RICHARDS, CARL W. RAUSCH, CHARLES
A. SANDERS AND J. RICHARD CROUT**

By their attorneys,

/s/ Michael D. Blanchard

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above pleading was electronically served upon the attorneys of record for all parties on January 31, 2006.

/s/ Michael D. Blanchard

Michael D. Blanchard